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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,966	05/01/2002	Masataka Nadaoka	2001-1915A	6249

513 7590 07/28/2004

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,966

Applicant(s)

NADAOKA ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/04/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-16 are so vague and indefinite that it is incomprehensible. The following are the best reasonable interpretation of the claims as presented by Applicant.

Claim 1 appears to be a method claim, however, no positive method steps have been recited.

It appears that claim 1 requires the use of some sort of chromatography device comprising a labeled layer/zone and a capture layer/zone having immobilized capture reagent. In use, it appears that a sample is added to the device and analytes are captured in the capture layer. Detection is made of both the captured fraction and the unreacted fraction. Claim 1 also appears to recite some sort of displacement assay where labeled reagent is displaced from a zone eluted from a column.

Claim 2 appears to recite that the amount of analyte is determined by measuring either the remainder of the bound fraction or the eluted fraction.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

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§ 2172.01. The claims are directed to a method; however, positive method steps have not been recited.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by DeLaCroix et al (US 5,206,177)

DeLaCroix discloses a device and method for detecting analytes from a sample comprising means for separating mobile detectable moiety from unreacted reaction component. The device comprises an optional sponge 13 which can be impregnated with a buffer, and may receive the sample being analyzed. The first zone 14 is positioned so that it receives sample which diffuses from sponge 13 when the sponge is used. Zone 14 contains a conjugate pad 15, and a matrix 16. Conjugate pad 15 contains the removable labeled analyte, labeled analyte analogue, or labeled binding partner. When the sample contacts this region, either by direct contact or by diffusion, the conjugate and the sample mix, and any reactions between analyte and binding partner take place. The mixture passes to matrix 16, which contains an immobilized form of a reagent. Generally the immobilized reagent is identical, or epitopically equivalent to the analyte being determined. When this is the case, the immobilized reagent must be present in an amount sufficient to bind essentially all of the labeled conjugate present in conjugate pad 15.

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This is necessary to provide for the situation where the sample contains none of the analyte being determined. In a displacement assay, conjugate pad 15 and matrix 16 will be of one piece because the immobilized reagent will already have bound to it the labeled analyte or analyte analogue. Second zone 19 contains two parts, but this is not necessarily so. Substrate pad 18 contains a substrate which reacts with the label on the labeled component to form a detectable signal. This may be, but need not be, an enzyme substrate. Trapper pad 20, which is key to the invention, is in fluid contact with the substrate pad 18, or, if 18 and 20 constitute one piece, this one piece second zone is in fluid contact with the first zone. The trapper pad 20 contains a means, such as ionic exchange paper, which traps either the reaction product of the label and substrate, or unreacted substrate. Finally, in fluid contact with the second zone 19 is the waste pad 22, which is adapted for receiving excess fluid. Further, it absorbs any materials which may be removed when the test strip is washed. The waste pad 22 can, alternatively, be used as a measuring point. When separation of detectable moiety and unreacted reaction component takes place in the second zone 19, the element which is not trapped can be washed into the waste pad. This element, rather than the trapped element, can be measured as well as, or in preference to, the trapped element. See column 6, line 12 through column 7, line 9.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

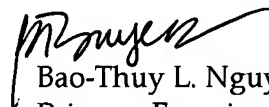
US 6,020,209

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
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7/26/04